IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. S HACKETT MARKETING LLC, a limited liability company d/b/a JUST ENHANCE, R THOMAS MARKETING LLC, a limited liability company, SHAWN HACKETT, an individual, and ROGER THOMAS, an individual, Defendants.	Hon. Michael A. Shipp Civil Action No. 3:17-04911 **ORDER OF PERMANENT INJUNCTION**

Having considered the United States' Motion for Default Judgment together with the memorandum of law in support thereof, and having further considered Defendants' opposition, if any, the Court concludes that the motion should be granted.

Defendants S Hackett Marketing LLC, a limited liability company doing business as Just Enhance; R Thomas Marketing LLC, a limited liability company; and Shawn Hackett and Roger Thomas, individuals, (collectively, "Defendants") have violated and are now violating the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399f, by: (1) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs that are neither approved under 21 U.S.C. § 355, nor exempt from approval; and (2) introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a).

Accordingly, it is ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint for Permanent Injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301–399f (the "Act").

3. Defendants violate 21 U.S.C. § 331(d), by introducing or delivering for introduction, and causing to be introduced or delivered for introduction, into interstate commerce new drugs within the meaning of 21 U.S.C. § 321(p) that are neither approved under 21 U.S.C. § 355, nor exempt from approval.

4. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of: 21 U.S.C. § 352(f)(1), because their labeling fails to bear adequate directions for use; and certain drugs are also misbranded under 21 U.S.C. § 352(a), because their labeling is false or misleading.

5. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, affiliates, and "doing business as" entities) (collectively, "Associated Persons"), who receive actual notice of this Order by personal service or otherwise, are permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly receiving, holding, distributing, or causing the distribution of any articles of drug, at or from 20 Passaic Street, Trenton, New Jersey; 15A Iron

Works Way, Trenton, New Jersey; 439 S. Broad Street, Trenton, New Jersey; 212 Centre, Trenton, New Jersey; 407 Wilfred Avenue, Trenton, New Jersey; 319 Rennie Street, Hamilton, New Jersey; 3704 White Plains Road, Bronx, New York; 525 S. 11th Avenue, Mount Vernon, New York; 710 E. 217 Street, Bronx, New York; 3722 White Plains Road, Bronx, New York; and 1023 E. 99th Street, Brooklyn, New York, or at or from any other locations at which Defendants now, or in the future, directly or indirectly receive, hold, distribute, or cause the distribution of articles of drug, including those locations provided by Defendants pursuant to the terms of Paragraph 6 ("Defendants' facilities"), unless and until all of the following occur:

a. An approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(a), (b), (j), or (i) is in effect for such drugs; or

b. Defendants retain, at Defendants' expense, an independent person or persons (the "Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and/or their families, and who, by reason of background, training, education, and experience, is qualified to inspect any of Defendants' facilities where Defendants' products are received and/or held to review the claims Defendants make for each of their products on websites registered to, owned, controlled by, or under the direction of Defendants now or in the future, including those listed in Appendix A ("Defendants' websites"), product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug;

i. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the identity and qualifications of the Expert within three (3) business days of retaining the Expert;

ii. The Expert shall perform a comprehensive review of Defendants' compliance with the Act, its implementing regulations, and this Order; and

iii. Defendants and/or the Expert shall remove all claims that cause Defendants' products to be drugs from all of Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug;

c. The Expert certifies in a written report, that includes a list of all locations the Expert inspected and a list of all materials he or she has reviewed, including, but not limited to, all Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug, whether Defendants are operating in compliance with the Act, its implementing regulations, and this Order;

i. The report shall include copies of all materials reviewed by the Expert; and

ii. The Expert shall submit the report concurrently to Defendants and FDA no later than ten (10) calendar days after completing this review;

d. Should the Expert identify any deficiencies in his or her report described in Paragraph 5(c):

i. Defendants shall report to FDA and the Expert in writing the actions they have taken to correct all such deficiencies; and

ii. The Expert shall certify in writing to FDA, based upon the Expert's further review and/or inspection(s), whether Defendants have omitted all claims from Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug, which cause Defendants'

products to be drugs under the Act;

e. Defendants shall provide FDA any additional information it requests after FDA's review of the Expert's report;

f. After FDA receives the certification from the Expert pursuant to Paragraph 5(c), FDA representatives may inspect some or all of Defendants' facilities, at FDA's discretion, to determine whether the requirements of this Order have been met and whether Defendants are operating in conformity with the Act, its implementing regulations, and this Order;

g. Defendants have paid all costs of FDA's inspections, investigations, supervision, analyses, examinations, and reviews with respect to Paragraph 5, at the rates set forth in Paragraph 14; and

h. FDA notifies Defendants in writing that they appear to be in compliance with the requirements set forth in Paragraphs 5(b)–(e) and (g). Under no circumstances shall FDA's silence be construed as a substitute for written notification.

6. Within ten (10) calendar days after entry of this Order, Defendants shall provide an affidavit to FDA listing all locations where Defendants' products are received, held, or distributed. Within twenty (20) calendar days after entry of this Order, Defendants shall recall and destroy, under FDA supervision and to FDA's satisfaction, unapproved new drugs and misbranded drugs that Defendants received, held, distributed, or caused the distribution of before entry of this Order. Defendants shall, under FDA supervision and to FDA's satisfaction, notify all affected consumers of the recall. Prior to destruction, Defendants must submit a written destruction plan to FDA and FDA must approve Defendants' destruction plan in writing before any destruction can take place. Under no circumstances shall FDA's silence be construed as a substitute for written notification. Defendants shall notify FDA in writing within ten (10)

calendar days of receiving any additional recalled products. Defendants shall hold the recalled products until FDA is available to supervise destruction. Defendants shall not dispose of any drugs in a manner contrary to the provisions of the Act, any other federal law, or the laws of any state or territory in which the drugs are disposed. Defendants shall bear the cost of the recall, destruction notification, and FDA supervision. The cost of FDA's participation and supervision under this Paragraph shall be borne by Defendants at the rates specified in Paragraph 14.

7. Upon resuming operations after complying with Paragraphs 5(b)–(e) and (g), and FDA has notified Defendants in writing pursuant to Paragraph 5(h), Defendants shall meet the following requirements:

a. Defendants shall select an independent laboratory that is without any personal or financial ties (other than a service contract) to Defendant and/or their families and that, by reason of background, training, education, or experience, is qualified to analyze articles of drug to determine whether the products contain sildenafil or any active pharmaceutical ingredient, and Defendants shall notify FDA in writing of the identity and qualifications of the laboratory within three (3) business days of retaining such laboratory. Thereafter:

i. For each lot of product that Defendants directly or indirectly receive or hold for distribution (directly or indirectly), Defendants shall have the laboratory conduct testing, using analytical methods acceptable to FDA, to verify that the lot does not contain sildenafil or any other active pharmaceutical ingredient. Defendants shall maintain copies of all records, including records provided to Defendants from the laboratory, documenting all laboratory analyses;

ii. Defendants shall not release for distribution any lot of product until they have received and reviewed the laboratory analyses conducted pursuant to this Paragraph, and

such analyses have verified that the lots do not contain sildenafil or any other active pharmaceutical ingredient;

iii. If any laboratory analysis conducted pursuant to this Paragraph detects the presence of sildenafil or any other active pharmaceutical ingredient, Defendants shall:

1. Have the laboratory contemporaneously provide to FDA and Defendants the results of those analyses within one (1) business day after the laboratory obtains such results; and

2. After FDA has approved in writing a written destruction plan from Defendants, Defendants shall, at Defendants' expense and under FDA's supervision, destroy all products from each lot that tested positive for the presence of sildenafil or any other active pharmaceutical ingredient; and

iv. If, after notifying FDA of the name of the laboratory retained to conduct testing pursuant to this Paragraph, Defendants terminate their service contract with the laboratory, Defendants shall notify FDA within three (3) business days of such termination, select another laboratory that meets the criteria in Paragraph 7(a) to conduct the testing described therein, and notify FDA in writing of the identity and qualifications of the newly retained laboratory within (3) business days of retaining such laboratory; and

b. Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' products at all of Defendants' facilities where product is held and of Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug, no less than once every six (6) months for a period of five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and

shall be without personal or financial ties (other than a consulting agreement with Defendants) to Defendants' officers or employees or their immediate families. The Auditor may be the same person or persons described as the Expert in Paragraph 5(b). Additionally:

i. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor within three (3) business days of retaining the Auditor;

ii. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") listing all locations the auditor inspected, listing all materials the auditor reviewed, including, but not limited to, all Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug, and analyzing whether Defendants' products and their websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug, are in compliance with the Act, its implementing regulations, and this Order, and identifying in detail any deviations from the foregoing ("Audit Report Observations");

iii. Each Audit Report shall also contain a written certification that the Auditor:

1. has personally reviewed all of Defendants' products and their websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug; and

2. has personally certified whether all of Defendants' products and Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug, comply with the requirements of the Act, its implementing regulations, and this Order;

3. has personally reviewed Defendants' laboratory testing results for each lot of product received, held, distributed, or caused to be distributed by Defendants and certified that the laboratory testing shows that all lots not destroyed pursuant to Paragraph 7 did not contain sildenafil or any other active pharmaceutical ingredient.

iv. As part of every Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations;

v. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than ten (10) calendar days after the date the audit inspections are completed;

vi. If any Audit Reports identify any deviations from the Act, applicable regulations, and/or this Order, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew;

vii. Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at Defendants' facilities and shall promptly make all Audit Reports and underlying data available to FDA upon request; and

viii. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within twenty (20) calendar days after receiving the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than twenty (20) calendar days, Defendants shall, within ten (10) calendar days after receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. The Correction Schedule must be reviewed and approved by FDA in writing prior to implementation. Under no

circumstances shall FDA's silence be construed as a substitute for written notification. Defendants shall complete all corrections according to the approved Correction Schedule. Within ten (10) calendar days after Defendants receive an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observations. Within two (2) calendar days after beginning that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected and their anticipated correction date.

8. If Defendants resume operations or engage in receiving, manufacturing, processing, packing, labeling, holding, distributing, or causing the distribution of any drug or dietary supplement, Defendants must comply with all provisions of the Act and its implementing regulations applicable to such products.

9. Upon entry of this Order, Defendants and all of their Associated Persons are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act that:

a. Violates 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any product that is a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

b. Violates 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a); and/or

c. Fails to implement and continuously maintain the requirements of this Order.

10. If, at any time after entry of this Order, FDA determines, based on the results of an inspection, a report submitted by Defendants, the Expert, the Auditor, the laboratory, or any other information, that Defendants have failed to comply with any provision of this Order, the Act, or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Order, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

a. Cease receiving, holding, distributing, and causing the distribution of all drug products;

b. Recall and/or destroy, at Defendants' expense, any drug products that are unapproved, misbranded, or otherwise in violation of this Order, the Act, or its implementing regulations;

c. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared, or laboratory testing program conducted, pursuant to this Order;

d. Submit additional reports or information to FDA as requested;

e. Submit additional samples to a qualified laboratory testing program;

f. Issue a safety alert; and/or

g. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants into compliance with this Order, the Act, and its implementing regulations.

The provisions of Paragraph 10 shall be apart from, and in addition to, all other remedies available to FDA.

11. Upon receipt of any order issued by FDA pursuant to Paragraph 10, Defendants

shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in Paragraph 10 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Order, the Act, and its implementing regulations, and that Defendants may resume operations. Under no circumstances shall FDA's silence be construed as a substitute for written notification. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 10 shall be borne by Defendants at the rates specified in Paragraph 14.

12. FDA shall be permitted, without prior notice and when FDA deems necessary, to make inspections of Defendants' facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Order, the Act, and its implementing regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, products, product labeling and promotional materials, websites, any other media owned or controlled by or related to Defendants, and other materials therein; take photographs and make video recordings; take samples of Defendants' products, containers, packaging material, labeling, and other materials; and examine and copy all records relating to receiving, holding, distributing, or causing the distribution of drugs. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

13. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, holding, distributing, or causing the distribution of Defendants' products. Defendants shall submit, within ten (10) calendar days, a copy of the materials FDA

requests, including, but not limited to, a list of all locations where any of Defendants' products are held; a list of all of Defendants' websites and any other media owned or controlled by or related to Defendants and/or their articles of drug; downloaded copies of Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug (on CD-ROM), and results of all laboratory analyses conducted pursuant to Paragraph 7, to FDA at the addresses specified in Paragraph 18.

14. Defendants shall pay all costs of all FDA inspections, investigations, analyses, examinations, sampling, reviews, document preparation, testing, travel (including the travel incurred by specialized investigatory and expert personnel), and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this Order, at the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to the United States Treasury within twenty (20) calendar days of receiving written notification from FDA of such costs. For the purposes of this Order, inspections include, but are not limited to, FDA review and analysis of Defendants' websites, product labeling and promotional materials, and any other media owned or controlled by or related to Defendants and/or their articles of drug. As of the date of this Order, these rates are: $93.26 per hour and fraction thereof per representative for inspection or investigative work; $111.77 per hour or fraction thereof per representative for analytical or review work; $0.535 per mile for travel by motor vehicle; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative and for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. Within ten (10) calendar days after the entry of this Order, Defendants shall provide a copy of this Order, by personal service or certified mail (return receipt requested), to each and all Associated Persons; post the Order on all of Defendants' websites and ensure the Order remains posted for as long as the Order remains in effect; post the Order in a conspicuous location in a common area at Defendants' facilities; hold a general meeting or series of smaller meetings for all employees, at which Defendants shall describe the terms and obligations of the Order; and provide FDA a copy of the agenda, list of attendees, and meeting minutes from the meeting. Within twenty (20) calendar days after the entry of this Order, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph and identifying the names and positions of all Associated Persons who have received a copy of this Order and the manner of notification. In the event that Defendants become associated, at any time after the entry of this Order, with new Associated Persons, Defendants shall: (a) immediately provide a copy of this Order to each such Associated Person by personal service or certified mail (return receipt requested), and (b) within ten (10) calendar days of such association, provide FDA an affidavit stating the fact and manner of their compliance with the provisions of this Paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Order pursuant to this Paragraph and the manner of such notification. Within ten (10) days of receiving a request from FDA for any information or documentation FDA deems necessary to evaluate compliance with this Paragraph, Defendants shall provide such information or documentation.

16. Defendants shall notify FDA in writing at the addresses specified in Paragraph 18, at least fifteen (15) calendar days before any change in ownership, character, or name of their business, such as dissolution, assignment, or sale resulting in the emergence of a successor

corporation, the creation or dissolution of subsidiaries, franchises, affiliates, or "doing business as" entities, or any other change in the organizational structure of S Hackett Marketing LLC or R Thomas Marketing LLC or in the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect compliance with this Order;

a. Defendants shall provide a copy of this Order to any potential successor or assignee at least fifteen (15) calendar days before any sale or assignment; and

b. Defendants shall furnish FDA with an affidavit stating the fact and manner of their compliance with Paragraph 16 no later than ten (10) calendar days before such assignment or change in ownership.

17. Defendants shall notify FDA in writing, at least ten (10) business days before the creation of a new website or link or reference, direct or indirect, to another website or other source that conveys information about Defendants' products. Defendants shall post a copy of this Order, in accordance with Paragraph 15, on any websites created after entry of this Order that convey information about Defendants' products. Within ten (10) calendar days of the creation of any new websites, Defendants shall provide to FDA an affidavit of compliance, stating the fact and manner of compliance with the provisions of this Paragraph.

18. All notifications, certifications, reports, correspondence, and other communications to FDA required under this Order shall be addressed to both the (1) District Director, New Jersey District Office, United States Food and Drug Administration, 10 Waterview Boulevard, Parsippany, New Jersey 07054, and (2) District Director, New York District Office, U.S. Food and Drug Administration, 158-15 Liberty Avenue, Room 2029, Jamaica, New York 11433, and shall prominently reference this Order, the case name, and civil action number.

19. Should Defendants fail to comply with any provision of this Order, the Act, or its implementing regulations, they shall pay to the United States of America nine thousand dollars ($9,000.00) in liquidated damages for each violation of this Order, the Act, and/or its implementing regulations; an additional nine hundred dollars ($900) in liquidated damages per day, per violation, for each violation of this Order, the Act, and/or its implementing regulations; and an amount equal to twice the retail value of any drugs distributed in violation of the Act, its implementing regulations, and/or this Order. Defendants understand and agree that the liquidated damages specified in this Paragraph are not punitive in nature and their imposition does not in any way limit Plaintiff's ability to seek, and the Court to impose, additional civil or criminal penalties based on conduct that may also be the basis for payment of liquidated damages.

20. Should Plaintiff bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse Plaintiff for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and court costs or any other fees relating to such contempt proceedings.

21. All decisions specified in this Order shall be vested in the discretion of FDA. FDA's decisions shall be final and, if challenged, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Order shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

22. This Court retains jurisdiction of this action for the purpose of enforcing or modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 30th day of August, 2018.

s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

APPENDIX A

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adultvending.org
africablackantking.net
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africanblackant.org
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qualityweave.com
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weekendprincepills.com
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whatmenlike.us
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xzenpills.com
yiyebacilang.com
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